NDA 50-667

M. W. Talbott, Ph.D.
Director
Medical Regulatory Affairs
Eli Lilly and Company
Lilly Research Laboratories
Indianapolis, Indiana 42685

DEC 31 1991

Dear Dr. Talbott:

Reference is made to your New Drug Application (NDA) dated August 27, 1990, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lorabid® (loracarbef) 100 mg/5mL and 200 mg/5mL Powder for Oral Suspension.

We also reference your amendments dated December 10 and 13, 1990; February 5 and 18, April 30, June 11, July 17 and 19, and October 29, 1991.

We have completed our review of this application, as amended, and have concluded that adequate data have been submitted to demonstrate the safety and effectiveness of this product when used as directed in the revised product labeling dated December 31, 1991 prepared by the FDA as discussed and agreed to by you in the telephone conversation with Dr. Susan Alpert of the FDA on December 31, 1991. Therefore, NDA 50-667 is approved, effective as of the date of this letter.

In addition, we also recognize your commitment from this teleconference that you will submit the following within 180 days of approval.

1. Submit dissolution data for the suspension formulations and commit to continue work with the Division to establish final analysis methodology.

Please submit 12 copies of the final printed labeling (FPL), identical to the revised draft labeling dated December 31, 1991, as soon as available. All copies should be individually mounted on heavy-weight paper or similar material. The submission should be designated for administrative purposes as "FPL for approved NDA 50-667." Approval by FDA of the submission is not required before the labeling may be used.

Please submit, in duplicate, the advertising copy you intend to use in your proposed introductory promotional and/or advertising campaign. Submit one copy to the Division of Anti-Infective Drug Products and the second copy to the Division of Drug Marketing, Advertising, and Communications, HFD-240, 5600 Fishers Lane, Rockville, Maryland, 20857. Submit all proposed materials in draft or mock-up form, not in final print. Do not use form FDA 2253 for this submission; that form is for routine use, not proposed materials.

If you have any questions regarding this NDA, please contact Mr. Carmen DeBellas, Project Management Staff, at 301-443-6797.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

/S/ 12-31-91

D. Bruce Burlington, M.D. 053
Deputy Director for Scientific and
Medical Affairs
Center for Drug Evaluation of Research

NDA 50-667/S-008
NDA 50-667/S-009

FEB 8 1995

M.W. Talbott, Ph.D.
Director
Worldwide Regulatory Affairs
Lilly Research Laboratories
A Division of Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Dr. Talbott:

Reference is made to your supplemental new drug applications (NDA's) dated August 9, 1994, for Lorabid (loracarbef) Oral Suspension 100 mg, NDA 50-667/S-008, and August 12, 1994, for Lorabid (loracarbef) Oral Suspension 200 mg, NDA 50-667/S-009, submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act.

These applications contain final printed labeling changing the mixing instructions on the cartons and bottle labels from " Add water to mark" to "Add one teaspoon (5 mL) of water. Mix well. Pour out contents". Also, the arrow pointing to the add water mark and the actual mark itself have been removed.

We have completed our review of these submissions and find these supplemental applications acceptable. Therefore, these applications are approved effective as of the date of this letter.

This approval affects only those changes specifically submitted in these applications. Other changes that may have been approved or are pending evaluation are not affected.

Should additional information relating to the safety and effectiveness of these drug products become available, further revision of the labeling may be required.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.

If you have any questions concerning these supplemental NDA's, please contact Mr. Carmen DeBellas, Project Manager, at 301-443-6797.

Sincerely yours,

Mtda for LG 2/6/95

Lillian Gavrilovich, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

CC:
Orig NDA
50-667

HF-2
HFD-100
HFD-80
HFD-230
HFD-240
HFD-500
HFD-638
HFD-730
HFD-520
HFD-520/SMO/Albrecht
HFD-520/MO/Girardi
HFD-520/CSO/DeBellas 2/6/95
HFD-520/LabelFile
APPROVAL

Concurrence:
HFD-520/SCSO/Bona 2/6/95
HFD-520/ActDivDir/Gavrilovich

DEC 31 1986

NDA 50-580

Norman W. Lavy, M.D.
E.R. Squibb & Sons, Inc.
P.O. Box 191
New Brunswick, NJ 08903

Dear Dr. Lavy:

Reference is made to your New Drug Application dated June 1, 1983 submitted pursuant to section 505(b) of the Federal Food, Drug and Cosmetic Act for Azactam (aztreonam) for Injection.

We also acknowledge receipt of your additional communications dated October 20, November 30, 1983; January 5, 16, 17, February 1, 15, April 19, 23, July 12, 16, August 16, 22, 30, September 10, 18, October 3, 10, November 26, and December 28, 1984; January 23, February 27, April 1, 11, May 9, 13, June 7, July 16, September 10, November 13, December 16, 1985 and January 10, 13, 28, February 10, 13, 24, October 28, November 6, December 10, 17, 21, 24, 29, 30, 1986.

We have completed review of this application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective as recommended in the final printed labeling numbered J4-140 submitted on December 30, 1986. Accordingly, the application is approved, effective on the date of this letter.

Please submit, in duplicate, the advertising copy which you intend to use in your proposed introductory promotional and/or advertising campaign. Please submit one copy to the Division of Anti-Infective Drug Products, and the second copy to the Division of Drug Advertising and Labeling, HFN-240, Room 10B-04, 5600 Fishers Lane, Rockville, Maryland 20857. Please submit all proposed materials in draft or mock-up form, not final print. Also, please do not use form FD-2253 for this submission; this form is for routine use, not proposed material.

Please submit one market package of the drug when available.

We remind you that you must comply with the requirements set forth under CFR 314.80 and 314.81 for an approved NDA.

Sincerely yours,

12/31/86

Elaine C. Esber, M.D.
Director
Office of Biologics Research and Review
Center for Drugs and Biologics

cc:
Orig NDA 50-580
NWK-DO
HFN-82
HFN-220
HFN-535
HFN-710
HFN-800/JMinor
HFN-815 12/30/86
HFN-815/CSO/KCreedon/12/30/86/11m/1887m
HFN-815/MO/GStanley
HFN-815/PHARM/SNAlam/JDavitt

NDA 50-580/S-019
NDA 50-632/S-003

JUN 25 1992

Mr. John F. Bedard
Executive Director
Worldwide Regulatory Affairs
Bristol-Myers Squibb
Pharmaceutical Research Institute
P.O. Box 4000
Princeton, New Jersey 08543-4000

Dear Mr. Bedard:

Reference is made to your supplemental New Drug Applications (NDA's) dated June 20, 1990, submitted pursuant to section 507 of the Federal Food, Drug, and Cosmetic Act for Azactam® (NDA 50-580/S-019, aztreonam for injection USP, and NDA 50-632/S-003, aztreonam injection).

These supplemental applications provided for the incorporation of pseudomembranous colitis statements to the **WARNINGS** and **ADVERSE REACTIONS** sections of the labeling for Azactam®.

In addition, reference is made to the Agency's approvable letter of September 30, 1991, which notified you of additional revisions to the **WARNINGS** section of the labeling necessary for its approval.

The labeling revisions incorporated in the final printed labeling dated January 21, 1992 (J4-231F and J4-269H) include all revisions specified in the Agency letters dated September 30, 1991. Accordingly, supplements S-019 and S-003 are approved effective as of the date of this letter.

This approval affects only those changes specifically submitted in these applications. Other changes which may have been approved or are pending are not affected.

Should additional information relating to the safety and effectiveness of these drug products become available, further revision of the labeling may be required.

We remind you that you must comply with the requirements set forth under 21 CFR 314.80 and 314.81 for an approved NDA.